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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/058,903	01/28/2002	Timothy Robert Hurley	A0000513-01-DRK	7220

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WARNER-LAMBERT COMPANY
2800 PLYMOUTH RD
ANN ARBOR, MI 48105

EXAMINER	
KHARE, DEVESH	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 04/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/058,903	HURLEY ET AL.	
	Examiner	Art Unit	
	Devesh Khare	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-6 and 8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *2-4* is/are allowed.

6)☒ Claim(s) *5,6 and 8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The amendment and remarks received on 08/03/2004 has been entered in view of the RCE request. Claims 3-5 have been amended. Claims 1 and 7 have been cancelled. New claim 8 has been added. The finality of the Office Action mailed on 06/03/2004 has been withdrawn.

Claims 2-6 and 8 are currently pending in this application.

The examiner withdraws the 35 U.S.C. 103(a) rejections as being unpatentable over Pande in view of Wirth et al., in response to applicant's remarks that "the structure of the claimed compounds is not simply different from that of pregabalin; there is no structural similarity at all between the claimed compounds and pregbalin" and " a person of skilled in the art would not have reasonable expectation that pregablin would undergo Maillard reaction with lactose to produce the specific claimed compounds that would have a biological activity that is same as or similar to that of pregabalin".

Objection

In claim 2, compound 3, line 1, the phrase "3,4?5" should be replaced by the phrase "3,4,5".

Appropriate correction is required.

35 U.S.C. 112, first paragraph rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5 and 6 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling the production of pregabalin saccharide conjugates, their pharmaceutical formulation, does not reasonably provide enablement for pregabalin saccharide conjugates, their pharmaceutical formulation as agents for the treatment of central nervous system disorders and central nervous system diseases such as anxiety and pain. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claims 5 and 6, are directed to a method for treating a subject having a central nervous system disorder or disease by administering to the subject a pharmaceutically effective amount of a compound of claim 5 (pregabalin saccharide conjugates, their pharmaceutical formulation). Dependent claim limitations include the central nervous system disorder or disease selected from depression, seizure, anxiety, pain, sleep disorder, consumptive disorder, psychosis, dyskinesia, Huntington's disease, or Parkinson's disease (claim 6).

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

The factors regarding undue experimentation have been summarized in *In re Wands,* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Circ. 1988) as follows:

(1) The quantity of experimentation necessary (time and expense);

(2) The amount of direction or guidance presented;

(3) The presence or absence of working examples of the invention;

(4) The nature of the invention;

(5) The state of the prior art;

(6) The predictability or unpredictability of the art;

(7) The breadth of the claims; and

(8) The relative skill of those in the art.

1. QUANTITY OF EXPERIMENTATION

With regard to factor one the quantity of experimentation needed, a method for treating a subject having a central nervous system disorder or disease by administering to the subject a pharmaceutically effective amount of a compound of claim 5 (pregabalin saccharide conjugates, their pharmaceutical formulation). At the very least, experimentation correlative to establishing a method for treating a subject having a central nervous system disorder or disease which is within scope of treating a subject having a central nervous system disorder or disease. The absence of specific disclosures or the correlation of data to support applicant's assertions, invites the skilled artisan to engage in undue experimentation, to treat a subject having a central nervous system disorder or disease.

2. GUIDANCE PROVIDED

There is little guidance given in the specification as to the specific use of a pharmaceutically effective amount of a compound of claim 5 (pregabalin saccharide conjugates, their pharmaceutical formulation) in a method for treating a subject having a central nervous system disorder or disease. This lack of guidance would indeed impose the burden of undue experimentation in determining the degree, if any, for the elimination of human health conditions set forth. There is not seen any guidance in the specification drawn to establishing a correlation between the use of a pharmaceutically effective amount of a compound of claim 5 (pregabalin saccharide conjugates, their pharmaceutical formulation) and a method for treating a subject having a central nervous system disorder or disease. No guidance to use compound of claim 5 (pregabalin saccharide conjugates, their pharmaceutical formulation) in a method for treating a subject having a central nervous system disorder or disease.

3. WORKING EXAMPLES IN SPECIFICATION

The EXAMPLES advanced in the instant specification are not seen as sufficient to support the breadth of the claims for treating a subject having a central nervous system disorder or disease. It is noted that Examples 1-5 provide the synthesis of said compounds and Examples 6-13 provide the compositions of the same.

4. NATURE OF THE INVENTION

It is known in this art that certain compounds have efficacy in treating specific conditions having a central nervous system disorder or disease. The exact mechanism of action and the effects of pregabalin, its derivatives, and pharmaceutically acceptable salts for

use in the treatment of mania and bipolar disorder is disclosed (see abstract) (Pande: U.S. Patent 6,359,005; cited in the Office Action dated 6/03/2004.

5. STATE OF THE PRIOR ART

The instant claims are drawn to a compound of claim 5 (pregabalin saccharide conjugates, their pharmaceutical formulation) intended to be used in treating specific conditions having a central nervous system disorder or disease. The following reference is cited to show the state of the prior art:

Pande ; U.S. Patent 6,359,005.

6. THE PREDICTABILITY OF THE ART

To extrapolate the data presented in the disclosure for the class of compounds compound of claim 5 (pregabalin saccharide conjugates, their pharmaceutical formulation), for the treatment of central nervous system disorders and central nervous system diseases such as anxiety and pains not seen to be enabled or taught in the prior art. Neither the specification nor the prior art provides adequate guidance for equivocating the treatment data for the pregabalin saccharide conjugates, their pharmaceutical formulation, for the treatment of central nervous system disorders and central nervous system diseases.

7. BREATH OF THE CLAIMS

Claims 2-4, wherein the pregabalin is covalently linked to a saccharide of claims 2 and 3, and the pharmaceutical formulation comprising at least one compound of claim 2 and a pharmaceutically acceptable carrier, excipient, or diluent thereof (claim 4). Claims 5

and 6, are directed to a method for treating a subject having a central nervous system disorder or disease by administering to the subject a pharmaceutically effective amount of a compound of claim 5 (pregabalin saccharide conjugates, their pharmaceutical formulation). Dependent claim limitations include the central nervous system disorder or disease selected from depression, seizure, anxiety, pain, sleep disorder, consumptive disorder, psychosis, dyskinesia, Huntington's disease, or Parkinson's disease (claim 6).

8. THE RELATIVE SKILL IN THE ART

The relative skill in the art as it relates to a method for treating a subject having a central nervous system disorder or disease by administering to the subject a pharmaceutically effective amount of a compound of claim 5 (pregabalin lactose conjugates, their pharmaceutical formulation), is that of a Ph.D. or M.D. level.

Presently, the instant specification is not seen to provide an enabling disclosure for the scope of the invention as set forth in claims, which encompass for treating a subject having a central nervous system disorder or disease with the compound of formula presented in claim 5. It is noted that Law requires that the disclosure of an application shall inform those skilled in the art how to use applicant's alleged discovery, not how to find out how to use it for themselves, see In re Gardner et al. 166 USPQ 138 (CCPA 1970). In the instant case, the amount of experimentation needed to verify the efficacy of the said compound of formula presented in claim 5 for treating a subject having a central nervous system disorder or disease would indeed be voluminous and unduly burdensome in view of the teachings of the instant disclosure.

35 U.S.C. 112, second paragraph rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 8 is rejected under the second paragraph of 35 U.S.C. 112, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "isolated form" in claim 8 is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Applicant should consistently set forth the identity of the compound in isolated form.

2. A review of the prior art revealed no references that could be appropriately applied of claims 2-4, wherein the pregabalin is covalently linked to a saccharide, and the pharmaceutical formulation comprising at least one compound of claim 2 and a pharmaceutically acceptable carrier, excipient, or diluent thereof (claim 4).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Devesh Khare whose telephone number is (571)272-0653. The examiner can normally be reached on Monday to Friday from 8:00 to 4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, Supervisory Patent Examiner, Art Unit 1623 can be reached at 571-272-0661. The official fax phone numbers for the organization where this application or proceeding is assigned is (703) 308-4556 or 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Devesh Khare, Ph.D.,J.D.
Art Unit 1623
January 21,2005

RICHARD L. RAYMOND
PRIMARY EXAMINER
ART UNIT 1624